

K083030

Section 5: 510(k) Summary

FEB - 5 2009

The following information is provided as required by 21 CFR § 807.87 for the TENS-EMS-14 510(k) premarket notification for and in accordance with FDA's "Guidance Document for Powered Muscle Stimulator 510(k)s", June 9, 1999 and "Guidance for Tens. 510(k) Content" Draft August 1994.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the TENS-EMS-14 is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices.

Applicant: EMSI
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Tampa, Florida 33619
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Registration Number: 3003573572

Contact: Cherita James
M Squared Associates, Inc
901 King Street, Suite 200
Alexandria, Virginia 22314
Phone: 703-562-9800 Ext. 257
Facsimile: 703-562-9797

Date of submission: April 4, 2008

Proprietary Name: TENS-EMS-14

Common Name: Powered Muscle Stimulator, Transcutaneous Nerve Stimulator

Classification Status: 21 CFR 890.5850, 21 CFR 890.5890

Product Code: IPF, GZJ

Panel: Physical Medicine, Neurology

Predicate Device: EMSI's TENS-EMS-14 is substantially equivalent, for the purpose of this 510(k), to other devices that have received 510(k) clearance for similar indications for use.

Device Description: The TENS-EMS-14 is a combination TENS and EMS device which delivers nerve or muscle stimulation by applying an electrical current to electrodes, which are attached on the patient's skin. The output and waveform is adjustable according to the intended treatment of patient. The stimulator has 2 output channels, accessed through jacks at the top of the housing, so that it may stimulate either 2 or 4 patient electrodes. The device is powered by 4 AA batteries. A patient compliance timer can memorize 60 sets of operation records; the total recordable time is 999 hours.

Intended Use: As prescribed by a physician for the following:

TENS- Transcutaneous Nerve Stimulation

- Symptomatic relief of chronic intractable pain
- Post traumatic and post surgical pain relief

EMS- Electrical Muscle Stimulation

- Relaxation of muscle spasm
- Increasing local blood circulation
- Muscle re-education
- Prevention or retardation of disuse atrophy
- Prevention of venous thrombosis of the calf muscles immediately after surgery
- Maintaining or increase range of motion

Discussion of performance testing: Based on the output measurements, calculations, and safety testing/inspection; the TENS-EMS-14 is safe with respect to electrical leakage current, electrode and lead wire safety, as well as output current and power density. Testing performed in accordance with the accepted FDA requirements of IEC 60601-1-2, Medical Electrical Equipment, Part 1: General Requirements for Safety. Collateral Standard: Electromagnetic Compatibility- Requirements and Test, found the TENS-EMS-14 passed all of the applicable test.

Technological Characteristics and Substantial Equivalence

Output specifications, device design, waveforms and programmability demonstrated the TENS-EMS-14 to be substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB - 5 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

EMSI
% Intertek Testing Services NA, Inc.
Mr. Daniel W. Lehtonen
2307 E. Aurora Road Unit B7
Twinsburg, Ohio 44087

Re: K083030

Trade/Device Name: TENS-EMS-14
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ, IPF
Dated: January 19, 2009
Received: January 21, 2009

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number: To be assigned

Device Name: TENS-EMS-14

Indications for Use:

TENS- Transcutaneous Nerve Stimulation

- Symptomatic relief of chronic intractable pain
- Post traumatic and post surgical pain relief

EMS- Electrical Muscle Stimulation

- Relaxation of muscle spasm
- Increasing local blood circulation
- Muscle re-education
- Prevention or retardation of disuse atrophy
- Prevention of venous thrombosis of the calf muscles immediately after surgery
- Maintaining or increase range of motion

Prescription Use X

AND/OR

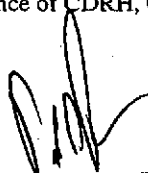
Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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